

Application Serial No.: 10/679,887
Polisetti et al.
Filed: October 6, 2003

Attorney Docket No.: 6511.204-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Dharma Rao Polisetti et al. Examiner: Joseph R. Kosack
Serial No.: 10/679,887 Group Art Unit: 1626
Filing Date: October 6, 2003 Confirmation No.: 3758
Title: ARYL CARBONYL DERIVATIVES AS THERAPEUTIC AGENTS

Commissioner for Patents
Mail Stop Petitions
P.O. Box 1450
Alexandria, VA 22313-1450

**Follow-Up Communication Pursuant to MPEP 2733 Regarding Patent Term
Adjustment (PTA) Indicated in Notice of Allowance**

Dear Sir:

On February 14, 2008, Applicants filed a five-page "Communication Pursuant to MPEP 2733 Regarding Patent Term Adjustment (PTA) Indicated in Notice of Allowance." Shortly thereafter, Applicants noticed that only the first page of this document was present in the Patent Application Information Retrieval (PAIR) system. On March 11, 2008, Applicants filed a second copy of the February 14th Communication along with a cover letter and a copy of the return postcard from the February 14th filing.

On August 5, 2008, Applicants filed a "Petition Pursuant to 37 C.F.R. 1.705(d)." In this petition, Applicants mentioned not yet having received a decision on the February 14th Communication. Finally, on June 23, 2009, Applicants received a "Decision on Request for Reconsideration of Patent Term Adjustment." In this paper, the Office of Petitions noted that, regarding the February 14th Communication, "The entire five (5) page document, including the signature page, has not been received to date."

Applicants wish to inform the Office that this paper does appear in PAIR, in its entirety, as of March 11, 2008. Applicants request consideration of this paper and a final determination of patent term adjustment. Applicants include, in this paper, an additional copy of the February 14th Communication.

Applicants believe no fee is required to timely file this paper. However, should any additional petition or fee be required for timely filing of this paper, Applicants hereby grants authorization to charge Deposit Account No. 14-1447, in the name of Novo Nordisk Inc., for any such required fee.

Respectfully submitted,

Date: July 22, 2009

/ Rosemarie R. Wilk-Orescan, Reg. No. 45,220 /

Rosemarie R. Wilk-Orescan
Registration No. 45,220
Novo Nordisk Inc.
Customer No. 23,650
(609) 987-5969

Application Serial No.: 10/679,887
Polisetti et al.
Filed: October 6, 2003
Express Mail Label No. EV732210662US

Attorney Docket No.: 6511.204-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Dharma Rao Polisetti et al. Examiner: Joseph R. Kosack
Serial No. 10/679,887 Group Art Unit: 1626
Filing Date: October 6, 2003 Confirmation No.: 3758
Title: ARYL CARBONYL DERIVATIVES AS THERAPEUTIC AGENTS

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**Communication Pursuant to MPEP 2733 Regarding Patent Term Adjustment
(PTA) Indicated in Notice of Allowance**

Dear Sir:

A Notice of Allowance was mailed on November 16, 2007, for the above identified patent application. One of the attachments to the Notice of Allowance was a Determination of Patent Term Adjustment under 35 USC § 154(b), which indicated the PTA is 326 days. This patent term adjustment is thought to be longer than appropriate. For the reasons described in greater detail below, it is believed the correct total PTA is 324 days.

USPTO Delay Days

Applicants respectfully submit the following instance qualifies as examination delay ("USPTO Delay Days") under 37 CFR § 1.703:

Three hundred twenty-six (326) days under 37 CFR § 1.703(a)(1)

Applicants agree with the Office that the patent term should be extended by 326 days according to 37 CFR § 1.703(a)(1). These 326 "USPTO Delay Days" arise for the number of days from the day after the date that is fourteen months after the date on which the application was filed under 35 USC § 111 (October 6, 2003) to the date of mailing of a notice of allowance (October 28, 2005).

Applicant Delay Days

Applicants respectfully submit the following instance may qualify as "Applicant Delay Days" under 37 CFR § 1.704:

Two (2) Days Under 37 CFR § 1.704(b)

On October 28, 2005, the Office mailed a Notice of Allowance to Applicants. The issue fee payment was received by the Office on January 30, 2006, being sent by first class mail under 37 CFR § 1.8 on January 27, 2006.

Under 37 CFR § 1.704(b),

"[A]pplicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of three months that are taken to reply to any notice or action by the Office ... measuring such three-month period from the date the notice of action was mailed [October 28, 2005] or given to the applicant, in which case the period of adjustment set forth in § 1.703 [326 days] shall be reduced by the number of days, if any [2 days], beginning on the day after the date that is three months after the date of mailing or transmission of the Office communication notifying the applicant of the rejection, objection, or other request [January 29, 2006] and ending on the date the reply was filed [January 30, 2006]."

Therefore, under 37 CFR § 1.704(b), the period of adjustment set forth in § 1.703 should be reduced by 2 days – corresponding to the period from January 29, 2006, through January 30, 2006.

Additional Disclosure

Applicants believe, based on the facts as outlined in the following paragraph, that the RCE dated August 29, 2007, was correctly filed and that the PTA was correctly calculated by the USPTO.

Specifically, on October 23, 2006, a RCE was submitted together with a Petition to Correct Inventorship pursuant to 37 C.F.R. § 1.48(b). Applicants' Petition was granted and corresponding corrections to the filing receipt and bibliographic data sheet were entered into the record in February 2007. Two telephonic interviews between the Examiner and Applicants' undersigned representative were held on April 2 and April 11, 2007, during which the Examiner requested certain amendments to the claims. Although no Interview Summary was generated for either of the April 2007 teleconferences, both are referenced in the Remarks submitted with Applicants' Amendment under 37 C.F.R. § 1.114 dated August 29, 2007, which reflect the Applicants' understanding that prosecution on the merits was closed. Notably, however, between the time of the miscellaneous communications from the PTO regarding the granting of Applicants' Petition (December 7, 2006) and the filing of the next RCE (August 29, 2007), the Examiner did not enter any substantive action on the merits, such as a Notice of Allowance, Final Rejection, or Office Action under *Ex parte Quayle* to close prosecution. Instead, the next papers entered into the file are the aforementioned RCE, an amendment, and an IDS, which were concurrently submitted on August 29, 2007. The Examiner entered and considered these documents, and a Notice of Allowance issued on November 16, 2007.

In compliance with the Applicants' duty of candor and good faith and out of an abundance of caution, Applicants note the USPTO did not issue a paper formally closing prosecution. Thus, an issue may be raised as to whether the RCE dated August 29, 2007,

was properly entered, and, if not, how the papers submitted on August 29, 2007, are to be treated.

If the USPTO were to determine the RCE was *improperly entered* (which Applicants do not concede), the Applicant should have been notified of the improper RCE and any amendment/reply should be entered. MPEP 706.07(h)(III)(A)(1). In this case, an adjustment to PTA as outlined below would be necessary. This improper RCE would not change the overall prosecution of the application, because the amendment and IDS were properly considered by the Examiner and the application was allowed on November 16, 2007. If the RCE dated August 29, 2007, were to be expunged from the record, and if the RCE and Petition to Correct Inventorship on October 23, 2006, were to be considered a "reply" as that term is used in 37 CFR § 1.704(c)(8), the Amendment and IDS filed on August 29, 2006, could be considered a "supplemental reply or other paper" that would invoke that section of the regulations. (Applicants' representative contacted the Office of Patent Legal Administration and was advised that an RCE is considered a reply under 35 USC § 132 with respect to the grounds of adjustment for patent term for examination delay under 37 CFR § 1.702(a)(2)). Accordingly, under this interpretation, a reduction of 310 days of PTA (from the filing of an RCE on October 23, 2006, to the filing of an Amendment and IDS on August 29, 2007) would be warranted.

Under these circumstances the calculation should also include an additional 266 days of "USPTO Delay Days". Under 37 CFR § 1.702(a)(2), "The term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to ... respond to a reply under 35 U.S.C. § 132 ... not later than four months after the date on which the reply was filed." As discussed in the paragraph above, the Office of Patent Legal Administration considers an RCE a reply under 35 USC § 132 with respect to the grounds of adjustment for patent term for examination delay under 37 CFR § 1.702(a)(2). These grounds of adjustment are applied in 37 CFR § 1.703(a)(2), wherein the number of "USPTO Delay Days" is calculated as the period from the day after the date that is four months after the date of the filing of the RCE

(February 24, 2006) to the date of mailing of the notice of allowance (November 16, 2007). This period of adjustment amounts to 266 "USPTO Delay Days".

This recalculation would thereby result in a net decrease of 44 days of PTA, i.e., from 326 days to 282 days, and would be further reduced by two (2) days, as set forth above.

CONCLUSION

As discussed above, the USPTO's determination of the period of adjustment due to examination delay under 37 CFR § 1.703(a)(1) is correctly stated at 326 days. However, Applicants believe this term should be reduced by two days. The correct patent term adjustment to date should be 324 days. Furthermore, depending upon the Office's treatment of the additional disclosure above, the correct patent term adjustment to date could possibly be reduced an additional 44 days to give 280 days. Applicants respectfully request that the PTO, in view of the foregoing additional disclosure, review the prosecution of the referenced application and reconsider the PTA allocation as it determines may be necessary.

Should the Office have any questions relating to the instant application, the Examiner is invited to telephone the undersigned to discuss any issues.

Respectfully submitted,

Date: February 14, 2008



Rosemarie R. Wilk-Orescan
Registration No. 45,220
Novo Nordisk Inc.
100 College Road West
Princeton, NJ 08540
(609) 987-5969

Application Serial No.: 10/679,887
Polisetti et al.
Filed: October 6, 2003
Express Mail Label No. EV732210662US

Attorney Docket No.: 6511.204-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Dharma Rao Polisetti et al. Examiner: Joseph R. Kosack
Serial No. 10/679,887 Group Art Unit: 1626
Filing Date: October 6, 2003 Confirmation No.: 3758
Title: ARYL CARBONYL DERIVATIVES AS THERAPEUTIC AGENTS

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**Communication Pursuant to MPEP 2733 Regarding Patent Term Adjustment
(PTA) Indicated in Notice of Allowance**

Dear Sir:

A Notice of Allowance was mailed on November 16, 2007, for the above identified patent application. One of the attachments to the Notice of Allowance was a Determination of Patent Term Adjustment under 35 USC § 154(b), which indicated the PTA is 326 days. This patent term adjustment is thought to be longer than appropriate. For the reasons described in greater detail below, it is believed the correct total PTA is 324 days.

USPTO Delay Days

Applicants respectfully submit the following instance qualifies as examination delay ("USPTO Delay Days") under 37 CFR § 1.703:

Three hundred twenty-six (326) days under 37 CFR § 1.703(a)(1)